FORM, SUPPLIER SELF-ASSESSMENT

Instructions: **This form consists of three (3) Sections: A, B and C.**
SECTION A- Form Initiation-Completed by Supplier Quality- This section includes the form Log Number and the evaluation type.
SECTION B- Preliminary Assessment- Completed by current or potential suppliers' materials, service or software to Teleflex that are in scope of the purchasing controls as defined in TG-000056. This will determine if the supplier meets TFX minimum evaluation requirements before proceeding.
SECTION C- Quality System Assessment- Completed only by suppliers who are ***not*** in possession of certifications (ISO), but Teleflex wishes to complete evaluation or re-evaluate.

SECTION A FORM INITIATION

To be completed By Global Supplier Quality/Facility Quality

Log Number: **Request Number from Global Supplier Quality inbox :(include "*Supplier Self-Assessment Number*" in the Subject)** **Global-Supplier-Quality@teleflex.com** **Or manage at facility quality level.**			
Evaluation Type:	☐	**Evaluation**	**Complete all sections (as applicable).**
	☐	**Re-Evaluation***	**Complete section C only** ***Completed if the TFX is expanding the scope of the supplier.**

SECTION B PRELIMINARY ASSESSMENT PART 1: To be completed by the supplier.			
Business Information			
Organization Name:			
Address:			
Organizations Website:			
Year company was established:		**Number of Employees:**	
Applicable business license/ permit numbers NAICS number SBA?			
Are you a manufacturer or a distributor of the product?			
Corporate/Parent company name (if applicable):			
Corporate/Parent company address:			
Do you have a Business Continuity Plan?		**IF NO, WILL YOU DEVELOP ONE FOR TELEFLEX?**	
Contact Details			
Primary Contact:	**Name:** **Title:** **Email Address:** **Telephone:**		
Secondary Contact:	**Name:** **Title:** **Email Address:** **Telephone:**		
CEO/Owner/President:	**Name:** **Title:** **Email Address:** **Telephone:**		
Quality Manager:	**Name:** **Title:** **Email Address:** **Telephone:**		
Corporate/Parent company contact (as applicable) or CEO/Owner:	**Name:** **Title:** **Email Address:** **Telephone:**		

Manufacturing/Services/Facilities N/A sections that are not applicable to the product/service you be providing to Teleflex.			
Do you hold the relevant certifications (ISO) for the product or service you will provide to Teleflex?	Choose an item	**IF NO, COMPLETE SECTION C ALSO.**	
Description of product or service you will provide to Teleflex:			
Are you currently providing other products/service to Teleflex?	Choose an item	**If yes, what products:**	
Are the items to be purchased also manufactured at this location?	Choose an item		
Manufacturing Facility Location(s):		**Is manufacturing site identifiable on the product labelling or other?**	Choose an item
Key Operations Performed:	Choose an item: Other (specify):		
Please list any outsourced (subcontracted) components/ products/services for Teleflex:			
Do you provide sterile products?	Choose an item	**If yes, do you sterilize the products you provide or outsource/subcontract the process?**	Choose an item
What type of sterilization process do you use?	☐ Other Specify:	**Is (are) the sterilization certificate(s) provided with the product?**	Choose an item
Is manufacturing completed under environmental controls/ clean room?	Choose an item	**State Controls/ Room Class:**	
Is a COC/ COA provided with the product?	Choose an item		
Service Provider (sterilization, testing and calibration)			
Is your facility accredited to the required standards? If yes, please attach copy.	Choose an item		
If you are a Calibration Provider, are your weights traceable to a National Standard? If yes, please attach evidence.	Choose an item		
General			
Are back-up copies of the following critical items below maintained, and location?			
Tooling Drawings / Files?	Choose an item	**Storage Location:** Choose an item:	

Manufacturing Procedures?	Choose an item	**Storage Location:**	Choose an item:
Information Technology Back-Up Files?	Choose an item	**Storage Location:**	Choose an item:
Quality System Records?	Choose an item	**Storage Location:**	Choose an item:
Reason for any N/A:			
Select regulatory agencies/competent authorities applicable to the product or service provided to Teleflex: **(Select and list reference numbers as applicable)**	☐ FDA ☐ CMDCAS ☐ ANVISA ☐ JPAL ☐ EU Notified Body ☐ Other		
Has a sole Authorized Representative been designated (only for finished product sold into the EU):	Choose an item		
Other regulatory references as applicable:			
Additional Certifications held: **e.g. ISO Certifications**			
Any major notifications such as FDA Warning Letter (483) or cease orders provided by regulatory bodies which are still enforced or have been lifted within the last twelve (12) months: **(provide details)**			

Changes to Your Organisation Experienced in the Last 24 Months

☐ Ownership ☐ Merger/Acquisition ☐ Name Change	☐ Manufacturing Location* ☐ Facility Resizing ☐ Capabilities	☐ Quality Organization ☐ Certification/Regulatory Status ☐ Design/Process Changes*	☐ Sterilization* ☐ Other – Specify: ☐ No Changes

*For Products/Services related to Teleflex only.
Describe any changes checked above. Attach additional pages if required.

Changes to Your Organisation Anticipated in the Next 12 Months

☐ Ownership ☐ Merger/Acquisition ☐ Name	☐ Manufacturing Location* ☐ Expansion/Reduction ☐ Capabilities	☐ Quality Organization ☐ Certification/Regulatory Status ☐ Design/Process Changes*	☐ Sterilization * ☐ Other – Specify: ☐ No changes

*For Products/Services related to Teleflex Only. Describe any changes checked above. Attach additional pages if required.

Additional Considerations (N/A sections that are not applicable)	
Does the component/product/part (substance) you will (or have in the past) provide to Teleflex contain any substances listed on the *Substances of Very High Concern (SVHC) Candidate List?* (REACH) greater than 0.1% concentration.	
Does the component/product/part you will (or have in the past) provide to Teleflex contain any CMRs and/or EDs as defined in the EU/MDR 2017/745 (REACH, CLP, BIOCIDE regulation)?	
Is there supporting evidence (testing certifications) to confirm the above claims?	Choose an item **If yes, please attach.**
Has an importer/authorized representative been assigned as applicable?	Choose an item **Please identify:**
Have UDI numbers been assigned to products?	Choose an item
Have the relevant Economic operators per EU_MDR been identified on EUDAMED (once available)?	Choose an item **Please list appropriate references**
Has an authorized representative been appointed? (if applicable)?	Choose an item **Please identify**:

SUPPLIER DECLARATION AND APPROVAL - DO NOT APPROVE IF REQUIRED TO COMPLETE SECTION C

THE INFORMATION PROVIDED IN THIS QUESTIONNAIRE IS TRUE AND ACCURATE TO THE BEST OF MY KNOWLEDGE

BY MY SIGNATURE, I AFFIRM THE INFORMATION PROVIDED IS CORRECT AND TRUE.

PRINTED NAME/DEPT	TITLE	SIGNATURE	DATE

SECTION B

PART 2: To be completed by Supplier Quality or facility quality (TFX)-Do Not Complete if Supplier is completing Section C.

SUPPLIER QUALITY ASSESSMENT REVIEW

Note 1: If a decision is made by Executive Leadership to accept supplier, attach evidence of agreement

Check Items	Result	Comments
Has the self-assessment been completed to a level acceptable to TFX?		
Are supporting documents acceptable?		
Is supplier acceptable based on the information provided? If no, please provide justification. See Note 1 in header.		
Has the Originator/Requestor and Global Procurement been notified of the decision?		

Supplier Disposition:

☐ Supplier evaluation acceptable ☐ Supplier additional review/ development required

☐ Recommend supplier audit ☐ Supplier does not meet the acceptance criteria

By my signature, I affirm the response from the supplier above to be original and agree with the decision made.

Printed Name	Title	Signature	Date
Supplier Quality			
Subject Matter Expert (SME) (refer to table 1 below)			
Procurement			
Other			
Executive Leadership (if not acceptable)			

Table 1

SME Function	Required for:
Sterility Assurance	Sterilization providers, specialized testing related to bioburden, toxicological and other product supporting tests
Research and Development	Raw material, semi-finished goods or contract manufacturing/sub-contractors
Regulatory	Required for providers of regulatory support, management of competent authorities, regulators and/ or notified bodies
Engineering	Required for specialized providers of tooling, equipment or where technical expertise on the product is required.

IT	Required where the product is includes specialized software or hardware
Quality Operation/ Engineering	required for special quality related products and services
Executive Management	Required to approve suppliers with exceptions/ conditions

SECTION C - QUALITY SYSTEM ASSESSMENT

PART 1: TO BE COMPLETED BY SUPPLIER

For suppliers who do not maintain any ISO certification, complete all sections of the form.

Changes to Your Organisation Experienced in the Last 24 Months

☐ Ownership	☐ Manufacturing Location*	☐ Quality Organization	☐ Sterilization*
☐ Merger/Acquisition	☐ Facility Resizing	☐ Certification/Regulatory Status	☐ Other – Specify:
☐ Name Change	☐ Capabilities	☐ Design/Process Changes*	☐ No Changes

***For Products/Services related to Teleflex only.**
Describe any changes checked above. Attach additional pages if required.

1	**Does the site maintain a quality manual?**	Choose an item	**Revision:**
2	**Is there a defined Quality policy?**	Choose an item	**Quality policy is:**
3	**Is there an approved Quality Manual?**	Choose an item	**Name and Revision:**
4	**Does management review periodically the quality objectives and quality system?**	Choose an item **Frequency:**	**Governing procedure reference:** **Revision:**
5	**Is there a defined process for communicating and/ or seeking approval of significant changes with suppliers?**	Choose an item	**Governing procedure reference:** **Revision:**
6	**Is there a Design Control Process that:** • **Defines design in-puts?** • **Defines design out-puts?** • **Demonstrates Design change control is documented?**	Choose an item	**Governing procedure(s) reference:** **Revision:**
7	**Is there a procedure governing the regulatory compliance of the products and maintenance of registrations?**	Choose an item	**Governing procedure reference:** **Revision:**
8	**Is there a defined process for the selection and management of suppliers of materials and services?**	Choose an item	**Governing procedure reference:** **Revision:**
9	**Is there a supplier audit process?**	Choose an item	**Governing procedure reference:** **Revision:**

10	**Materials supplied (as applicable to Teleflex) are managed by:**	☐ Incoming inspection ☐ Certificate of analysis ☐ Dock to stock ☐ Other (please specify)	**Governing procedure reference:** **Revision:**
11	**Is manufacture of the products supported by:** • **Custom built equipment?**	Choose an item	**Governing procedure reference:** **Revision:**
	• **Environmental controls?**	Choose an item	**Governing procedure reference:** **Revision:**
	• **Are environmental controls monitored?**	Choose an item	**Governing procedure reference:** **Revision:**
	• **Calibration and maintenance program in place?**	Choose an item	**Governing procedure reference:** **Revision:**
	• **Statistical techniques used to support sampling and inspections?**	Choose an item	**Governing procedure reference:** **Revision:**
12	**Is there a procedure for verification and validation activities?** **If applicable are processes validated at your facility?**	Choose an item	**Governing procedure reference:** **Revision:**
13	**Is there a standard re-work process covered in the production that is:** • **Recorded in the DMR?** • **Is approval required per rework?**	Choose an item Choose an item	**Governing procedure reference:** **Revision:**
14	**Is there a defined process for documenting Non-conformances (NC)?** **Average number of NC per month:**	Choose an item	**Governing procedure reference:** **Revision:**
15	**Is there a defined process for documenting Corrective and Preventative Actions (CAPA)?**	Choose an item	**Governing procedure reference:** **Revision:**
16	**Is there a defined process for documenting Customer Complaints/ SCARs?** **Is there a metric/ KPI for response to SCARs?** **If so, what is the target response time?**	Choose an item Choose an item Choose an item	**Governing procedure reference:** **Revision:**
17	**Is there a documented approach to employee training that identifies training requirements and frequency?**	Choose an item	**Governing procedure reference:** **Revision:**
18	**Is there a documented record retention process?** **Retention period:**	Choose an item	**Governing procedure reference:** **Revision:**
19	**Is there a process and schedule for internal audits?**	Choose an item	**Governing procedure reference:** **Revision:**

SUPPLIER DECLARATION AND APPROVAL THE INFORMATION PROVIDED IN THIS QUESTIONNAIRE IS TRUE AND ACCURATE TO THE BEST OF MY KNOWLEDGE. *BY MY SIGNATURE, I AFFIRM THE INFORMATION PROVIDED IS CORRECT AND TRUE.*			
PRINTED NAME/DEPT	**TITLE**	**SIGNATURE**	**DATE**

SECTION C **PART 2: To be completed by Supplier Quality or facility quality (TFX)**		
SUPPLIER QUALITY ASSESSMENT REVIEW **Note 1: If a decision is made by Executive Leadership to accept supplier, attach evidence of agreement and approval.**		
Check Items	**Result**	**Comments**
Has the self-assessment been completed to a level acceptable to TFX?		
Are supporting documents acceptable?		
Is supplier acceptable based on the information provided? If no, please provide justification. See Note 1 in header.		
Has the Originator/Requestor and Global Procurement been notified of the decision?		
Supplier Disposition: ☐ Supplier evaluation acceptable ☐ Supplier additional review/ development required ☐ Recommend supplier audit ☐ Supplier does not meet the acceptance criteria		

By my signature, I affirm the response from the supplier above to be original and agree with the decision made.			
Printed Name	**Title**	**Signature**	**Date**
Supplier Quality/Facility Quality			
SME (refer to table 1) Click or tap here to enter text.			
Procurement			
Other			
Executive Leadership (if not acceptable)			